

REMARKS

In the Office Action of October 9, 2003, the Examiner rejected claims 1-9, 11-15, 17-34 under 35 U.S.C. §112, second paragraph. Applicant amended these claims to provide positive recitations of a light source and a light detector to overcome this rejection. Applicant also amended the claims to overcome various the informalities cited by the Examiner.

Applicant also amended the above claims to overcome a provisional double patenting rejection under 35 U.S.C. §101.

The Examiner rejected claims 1, 2, 6-9, 11-15, 17, 18, 29-35 under 35 U.S.C. §103(a) as obvious over US Patent 5,853,370 to Chance et al . The Examiner also rejected claims 3-9, 11-15, 17, 18, 29-34 under 35 U.S.C. §103(a) as obvious over US Patent 5,853,370 to Chance et al in view of US Patent 5,845,639 to Hochman et al. The Examiner also rejected claims 19-24 under 35 U.S.C. §103 (a) as obvious over US Patent 5,583,370 to Chance et al. in view of US Patent 5,564,417 to Chance et al. The Examiner also rejected claims 25-28 under 35 U.S.C. §103(a) as obvious over US Patent 5,583,370 to Chance et al. in view of US Patent 5,807,263 to Chance et al. Applicant respectfully disagrees with these rejections.

In the present application, Professor Chance disclosed a novel system and method directed to examination of breast tissue using visible or infra-red light. The optical examination can be used alone to detect and characterize a breast tumor, or can be used in combination with X-ray mammography, ultrasound examination, or a needle biopsy. The novel optical technique can employ one or several optical modules positioned on the right or left breast of a female patient placed in different positions. The patient may be sitting upright supporting the examined breast by the optical module, or may be lying face down with the breast on the optical module pad. Alternatively, the patient may be lying supine face up with the breast spread over the chest as evenly as possible.

As acknowledged by the Examiner, the original claims differed from the disclosures provided in US Patents 5,853,370, 5,807,263 or 5,564,417 by Chance.

Applicant has further amended the above claims to recite further patentable features to overcome any rejection under 35 U.S.C. §103(a).

In US Patent 5,845,639, Hochman et al. disclose methods and apparatus that significantly differ from the present invention, and significantly differ from the above mentioned patents by Professor Chance. US Patent 5,845,639 discloses methods for optically imaging blood flow changes, blood flow characteristics and changes in the oxygenation of blood in an area of brain of spinal tissue (and is not directed to breast tissue examination). The entire area of interest is illuminated uniformly (non-uniformity seem to be undesirable) with electromagnetic radiation(emr) in the visible or infrared regions of the spectrum. Then, the system acquires a control image representative of the emr absorption of the area of interest. A subsequent image representative of the emr absorption is compared to the control image to detect changes in the emr absorption that are indicative of changes in blood flow, changes in blood flow characteristics, or changes in blood oxygenation in the area of interest.

Specifically, Hochman illuminates an area of interest with uniform intensity electromagnetic radiation (emr in the visible and infrared regions of the spectrum), acquires a series of control frames representative of the emr absorption of the area of interest in the absence of a fluorescent dye and processes the frames to produce an image using a large area detector (e.g., a CCD). As disclosed in col. 16, line 48 through col. 17, line 15 of US Patent 5,845,639 Hochman teaches the following:

The inventive apparatus includes a means for obtaining an analog video signal of the cortex or area of interest. A preferred device for obtaining an analog video signal is a charge coupled device (CCD) video camera which creates an output video signal at 30 Hz having, for example, 512 horizontal lines per frame using standard RS 170 convention. One such device is a CCD-72 Solid State Camera (Dage-MIT Inc., Michigan City, Ind.) and another such device is a COHU 6500 (COHU, San Diego Calif.).

The area of interest must be evenly illuminated to better adjust the signal over a full dynamic range. If there is uneven illumination in the area of interest, it will limit the dynamic range. Preferably a high intensity and diffuse or even lighting system is used. Techniques to obtain even illumination over the area of interest include, for example, diffuse lighting, image processing algorithms to compensate for uneven illumination on a digitized image, a constant shade gray image marker point in the area of interest as a control point, a wavelength cutoff filter in front of the camera and/or emr source, or combinations thereof.

Preferably, a regulated power supply will prevent fluctuations in emr sources. A footplate system is an optical glass (sterile) contacting and covering the area of interest to provide a flatter contour. The footplate also retards tissue movement.

The analog signal must first be adjusted to maximize sensitivity of detection (at the level of the analog signal and before digitizing) to amplify the signal and spread the signal across the full possible dynamic range, thereby increasing sensitivity of the apparatus. 60 Hz noise (such as from A.C. power lines) is filtered out in the camera control box by an analog filter. Such adjustments further serve to enhance, amplify and condition the analog signal from the CCD. One means for properly adjusting the input analog signal is to digitize this signal at video speed (30 Hz), and view the area of interest as a digitized image that is converted back to analog. (Col. 16, line 48 through col. 17, line 15; emphasis ours)

Therefore, the teaching provided in US Patent 5,845,639 to Hochman et al. differs significantly from the present invention or from the above mentioned patents by Professor Chance. The above claims were amended to further emphasize several patentable differences between the pending claims and the cited prior art.

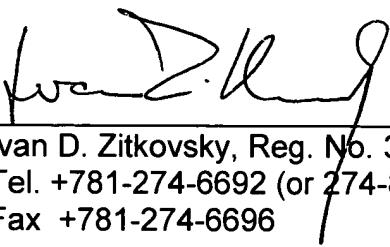
Accordingly, all claims are now in condition for allowance and such action is respectively requested. Should there be any outstanding issue left, the Examiner is respectfully invited to call the undersigned to resolve such issues.

Applicant : Britton Chance
Serial No. : 09/622,184
Page : 16

Attorney's Docket No.: 08326-045002

Enclosed are a Petition for Extension of Time and a check for \$475.00. Please apply any other charges or credits to Deposit Account No. 06-1050.

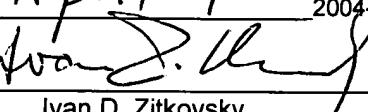
Respectfully submitted,



Ivan D. Zitkovsky, Reg. No. 37,482
Tel. +781-274-6692 (or 274-8064)
Fax +781-274-6696

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

April 9 2004

Ivan D. Zitkovsky

All correspondence to:

John N. Williams, Esq.
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

Telephone: (617) 542-5070
Facsimile: (617) 542-8906